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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,684	08/06/2001	Ramaswamy Narayanan	6818-24	1544

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EXAMINER

DAVIS, MINH TAM B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/923,684

Applicant(s)

NARAYANAN, RAMASWAMY

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

It is noted that the claims of the instant application have been determined to include linking claims 1, 25, 31 and 41. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 25, 31 and 41. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

This application contains claims directed to the following patentably distinct inventions linked by claims 1, 25, 31 and 41:

Groups 1-2. Claims 1-2, 5-9, 14-16, 24 drawn to a method for detecting colon cancer, comprising detecting the presence of a SIM2 nucleic acid marker of SEQ ID NO:1 or 2, using an oligonucleotide probe in Northern blot, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

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Groups 3-4. Claims 1-2, 3, 6-9, 14-16, 24 drawn to a method for detecting prostate cancer, comprising detecting the presence of a SIM2 nucleic acid marker of SEQ ID NO:1 or 2, using an oligonucleotide probe in Northern blot, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 5-6. Claims 1-2, 4, 6-9, 14-16, 24 drawn to a method for detecting pancreatic cancer, comprising detecting the presence of a SIM2 nucleic acid marker of SEQ ID NO:1 or 2, using an oligonucleotide probe in Northern blot, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 7-8. Claims 1-2, 5-9, 10-13, 24, drawn to a method for detecting colon cancer, comprising detecting the presence of a SIM2 nucleic acid marker of SEQ ID NO:1 or 2, using one or two PCR primers of SEQ ID NO: 7-8, 15-16, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 9-10. Claims 1-2, 3, 6-9, 10-13, 24, drawn to a method for detecting prostate cancer, comprising detecting the presence of a SIM2 nucleic acid marker of SEQ ID NO:1 or 2, using one or two PCR primers of SEQ ID NO: 7-8, 15-16, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 11-12. Claims 1-2, 4, 6-9, 10-13, 24, drawn to a method for detecting pancreatic cancer, comprising detecting the presence of a SIM2 nucleic acid marker of

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SEQ ID NO:1 or 2, using one or two PCR primers of SEQ ID NO: 7-8, 15-16, classified in class 435, subclass 6. A method detecting each of the nucleic acid marker of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 13-14. Claims 1, 17-24, drawn to a method for detecting colon cancer, comprising detecting the presence of a SIM2 protein marker of SEQ ID NO:3 or 4, using an antibody, classified in class 435, subclass 7.1. A method detecting each of the protein marker of SEQ ID NO: 3 or 4 constitutes a single invention.

Groups 15-16. Claims 1, 17-24, drawn to a method for detecting prostate cancer, comprising detecting the presence of a SIM2 protein marker of SEQ ID NO:3 or 4, using an antibody, classified in class 435, subclass 7.1. A method detecting each of the protein marker of SEQ ID NO: 3 or 4 constitutes a single invention.

Groups 17-18. Claims 1, 17-24, drawn to a method for detecting pancreatic cancer, comprising detecting the presence of a SIM2 protein marker of SEQ ID NO:3 or 4, using an antibody, classified in class 435, subclass 7.1. A method detecting each of the protein marker of SEQ ID NO: 3 or 4 constitutes a single invention.

Groups 19-20. Claim 25, drawn to a method for increasing the protein level of SIM2 of SEQ ID NO:3 or 4, classified in class 514, subclass 2. A method for increasing the protein expression of each of the SIM2 protein of SEQ ID NO:3 or 4 constitutes a single invention.

Groups 21-22. Claim 25, drawn to a method for decreasing the protein level of SIM2 of SEQ ID NO:3 or 4, classified in class 514, subclass 2. A method for decreasing

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the protein expression of each of the SIM2 protein of SEQ ID NO:3 or 4 constitutes a single invention.

Groups 23-24. Claim 25, drawn to a method for increasing the mRNA level of SIM2 gene of SEQ ID NO: 1 or 2, classified in class 514, subclass 44. A method for increasing the mRNA level of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 25-26. Claims 25-30, drawn to a method for decreasing the mRNA level of SIM2 of SEQ ID NO: 1 or 2, classified in class 514, subclass 44. A method for decreasing the mRNA level of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 27-28. Claims 31-37, drawn to a method for identifying a compound that increases the mRNA level of a SIM2 gene of SEQ ID NO:1 or 2, classified in class 435, subclass 6. A method for identifying a compound that increases the mRNA level of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 29-30. Claims 31-37, drawn to a method for identifying a compound that decreases the mRNA level of a SIM2 gene of SEQ ID NO:1 or 2, classified in class 435, subclass 6. A method for identifying a compound that decreases the mRNA level of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 31-32. Claims 31-37, drawn to a method for identifying a compound that increases the protein expression of a SIM2 gene of SEQ ID NO:1 or 2, classified in class 435, subclass 7.1. A method for identifying a compound that increases the protein

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expression of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 33-34. Claims 31-37, drawn to a method for identifying a compound that decreases the protein expression of a SIM2 gene of SEQ ID NO:1 or 2, classified in class 435, subclass 7.1. A method for identifying a compound that decreases the protein expression of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 35-36. Claims 41-51, drawn to a method for reducing the growth rate of colon cancer, using an agent that inhibits the expression of SIM2, which is the antisense oligonucleotide of SEQ ID NO:11 or 12, classified in class 514, subclass 44. A method using each of the oligonucleotide constitutes a single invention.

Groups 39-40. Claims 41-51, drawn to a method for reducing the growth rate of prostate cancer, using an agent that inhibits the expression of SIM2, which is the antisense oligonucleotide of SEQ ID NO:11 or 12, classified in class 514, subclass 44. A method using each of the oligonucleotide constitutes a single invention.

Groups 41-42. Claims 41-51, drawn to a method for reducing the growth rate of pancreatic cancer, using an agent that inhibits the expression of SIM2, which is the antisense oligonucleotide of SEQ ID NO:11 or 12, classified in class 514, subclass 44. A method using each of the oligonucleotide constitutes a single invention.

Groups 43-44. Claims 52-53, drawn to a kit comprising an agent that increases the expression of the SIM2 gene of SEQ ID NO:1 or 2, classified in class 536, subclass

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24.3. A kti comprising an agent that increases the expression of each of the SIM2 gene of SEQ ID NO:1 or 2 constitutes a single invention.

Groups 45-46. Claims 52-58, drawn to a kit comprising an agent that decreases the expression of the SIM2 gene, which is the antisense oligonucleotide of SEQ ID NO:11 or 12, classified in class 536, subclass 24.3. A kit comprising each of the oligonucleotide constitutes a single invention.

In addition, upon election of any of groups 7-12, further election of the following patentably distinct species:

Any one or any combination of SEQ ID NO: 7, 8, 15, 16.

The inventions are distinct, each from each other because of the following reasons:

Inventions (43-46) and (1-42) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case, an antisense oligonucleotide sequence could be used for the detection of similar DNA or RNA sequences, for detecting and treating diseases.

The products of groups 43-46 are patentably distinct, because they are drawn to entirely different biochemicals, having different structures, biological properties and activities.



The methods of groups 1-42 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The species primers are distinct because they have different structure.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

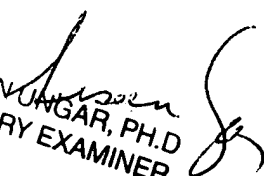
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

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MINH TAM DAVIS

February 28, 2003

  
SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER